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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PAR PHARMACEUTICAL, INC., and PAR STERILE PRODUCTS, LLC, Plaintiffs, v. QUVA PHARMA, INC., STUART HINCHEN, PETER JENKINS, and MIKE RUTKOWSKI, Defendants.	Civil Action No. 3:17-cv-06115-BRM-DEA ***Filed Electronically*** **HIGHLY CONFIDENTIAL**

DEFENDANTS' SUPPLEMENTAL BRIEF
IN OPPOSITION TO PLAINTIFFS'
MOTION FOR PRELIMINARY INJUNCTION

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Pursuant to the Court's request, the QuVa Defendants submit this Supplemental Brief in opposition to Par's Motion for Preliminary Injunction.

The APS/EM Plans. At oral argument, it was crystal clear that Par had abandoned its original vasopressin trade secret misappropriation claims. Par's case now focuses on alleged misappropriation of its "trade secrets" regarding its APS and EM Master Plans (and the subsequent deletion of documents regarding those plans by former QuVa employee Stephen Rhoades).[1]

The Court should hold that Par has not established a likelihood of success on its claims regarding the APS and EM Master Plans (hereafter, "the Plans") for at least two reasons: 1) the Plans ***are not trade secrets*** because they are "industry standard" high level policy documents containing public FDA recommendations, and Par did not derive independent economic value from maintaining their secrecy; and 2) to the extent the Plans contained substantive information directed to Par-specific policies, that information was not useful to, or used by, QuVa. *Dana Ltd. v. Am. Axle & Mfg. Holdings*, No. 10-cv-450, 2013 U.S. Dist. LEXIS 116899, *65-66 (W.D. Mich. Aug. 19, 2013) (holding use of public information from trade secret document was not misappropriation).

To put the dispute in context, an APS Plan sets high level parameters (based

[1] Mr. Rhoades's spoliation (if any) should not be imputed to QuVa, as discussed in QuVa's Response to Par's Supplemental Brief on this issue (Dkt. 142).

on regulatory guidelines and policies) for testing an aseptic process for contamination and aids in evaluating "worst case" scenarios for that specific process. (Ex. 424, ¶ 43; Ex. 307.) Similarly, an EM Plan implements regulatory guidelines for monitoring the environment of a sterile manufacturing facility. (Id., ¶ 53; Ex. 306). Not unexpectedly, both plans contain a significant amount of general information that is set forth in various regulatory and other public documents.[2] Importantly, it is this public information that QuVa stands accused of copying. And while QuVa does not dispute that this type of information was apparently copied by the consultant who finalized the plan, ***it strenuously disputes that the copied information contains Par trade secrets***.

To the extent Par's Plans include details relating to Par's manufacturing processes and equipment, none of *that* information appears in QuVa's plans.[3] (Ex. 424, ¶¶ 23-25, 53.) Indeed, Par has not rebutted QuVa's evidence that the substantive

[redacted]

[2] Par's EM plan lists eleven industry and regulatory references from which it was derived. (Ex. 144 at §6.0, pages 7-8/24; QuVa Slide 27.)

[3] Nor could it given the differences in the way the companies manufacture their products. (QuVa Slides 13-14.)

[redacted]

With respect to the value of Par's Plans, Par has represented to the Court, ***without any support whatsoever***, [redacted] These allegations are wrong and directly contradicted by documents that Par withheld during discovery. [redacted] Second, Par's own documents show: [redacted] (QuVa Slides 32-34.) In sum, Par has now exaggerated the value of the plans in its zeal to claim them as trade secrets.

Further, to enjoin QuVa based on misappropriation of Par's APS and EM Plans would be to reward Par's discovery misconduct. The Court recently held that Par improperly failed to identify its Plans as trade secrets during expedited discovery. (Dkt. 136 at 10-14.) However, the Court also held that QuVa was not prejudiced because QuVa refuted Par's arguments that Defendant misappropriated any alleged trade secrets in those plans on the basis that: 1) the copied material in

QuVa's plans was drawn from public guidance documents and was merely high level boilerplate; and 2) the substantive aspects of QuVa's plans were entirely different from Par's. (Dkt. 88 at 20-23; Dkt. 136 at 15-16; Ex. 424, ¶¶ 21-54.)

After the Court ruled on QuVa's motion, QuVa learned for the first time in conjunction with Mr. Rhoades's deposition that previously unproduced Par documents showed: 1) Par's motion papers misrepresented the value of these Plans to both Par and QuVa; and 2) Par did not consider its Plans to be its trade secrets (as discussed above). Although the extent of the prejudice to QuVa due to Par's discovery abuses is still unknown, it is clear that QuVa was deprived of information during discovery that directly discredits Par's claims.[4] Thus, any finding that QuVa misappropriated trade secrets regarding Par's APS and EM plans would be contrary to the Court's holding that QuVa was not prejudiced by Par's discovery violations.

Irreparable Harm. Par has introduced ***zero evidence of irreparable harm*** relating to any QuVa product besides vasopressin. Consequently, there can be no injunction based on any other product. *Select Med. Corp. v. Hardaway*, No. 05-cv-3341, 2006 U.S. Dist. LEXIS 15326, *27 (E.D. Pa. March 31, 2006).

With respect to vasopressin, Par cannot meet its burden of establishing "a clear showing of immediate irreparable injury." Par has failed to rebut the case law

[4] There is also no evidence in the record about how long it took Par to create its Plans or whether it took steps to protect the confidentiality of them over time.

or Dr. Rao's testimony that monetary damages for lost sales of Par's product can be quantified using accepted economic techniques, as can damages for price erosion. (Dkt. 88 at 33-35; Ex. 427, ¶¶ 18-25.) Par instead focuses on speculative arguments about lost investment opportunities, inability to raise capital and harm to Endo's stock price. *Pruvit Ventures, Inc. v. ForeverGreen Int'l LLC*, No. 15-cv-571, 2015 *U.S. Dist. LEXIS* 174982, *15 (E.D. Tex. Dec. 23, 2015) (rejecting these types of "damages" as irreparable). These alleged harms pose no immediate threat to Par and thus cannot be the basis for an irreparable harm finding. *INDECS Corp. v. Claim Doc,* No. 16-cv-4421, 2017 U.S. Dist. LEXIS 40952, *7-8 (D.N.J. Mar. 21, 2017).

Scope of the Injunction. Par seeks an open-ended injunction prohibiting QuVa from selling six currently marketed products and vasopressin. (Par Slide 32.) However, the temporal scope of the injunction must be limited to the time required for QuVa to develop new plans without access to Par's plans. *SI Handling Sys. v. Heisley*, 753 *F.2d* 1244, 1266 (3d Cir. 1985) ("the trade secret injunction lasts only so long as is necessary to negate the advantage the misappropriator would otherwise obtain by foregoing independent development"). The ***only*** evidence in the record that addresses this consideration is that plans could be independently developed in 40-60 hours each. (Ex. 424, ¶ 13.) Par and its expert Dr. Miller had an opportunity to rebut this evidence in its Reply submission, but failed to do so. Thus, any injunction should be limited in scope to 40-60 hours.

s/ David C. Kistler

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